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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
10/05/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/569,160	ASMUSSEN ET AL.	
	Examiner	Art Unit	
	MICAH-PAUL YOUNG	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 July 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,7-12,14-24 and 27-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,7-12,14-24 and 27-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/30/10 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 2, 7-12, 14-24, and 27-41 rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Chen et al (US 2003/0068378 hereafter '378) in view of Gilis et al (USPN 6,099,863 hereafter '863) and Uekama et al (USPN 5,904,929 hereafter '929).

The '378 application discloses a fast dissolving film or sheet formulation for buccal administration [abstract, 0028]. The film or sheet like formulation comprises from 0.7-75%, more preferably about 1 to about 30% [0061, Tables 5 and 7]. The film comprises multiple layers including a packaging layer that is insoluble to the active agent [Figure 3, 0058]. The film comprises fillers, disintegrants and is soluble in water allowing for rapid disintegration from 1-second to 5 minutes [0054, 0058, 0060, Example 1-3, claims]. The polymer content of the film strips is approximately 21 % [Table 5]. The film strips have a thickness up to 20 mil, approximately 0.5 mm [0059]. The active agents include a wide variety of compounds that can used in a variety of therapy methods including anti-Parkinson drugs, antidepressants, sleeping aids, central nervous system active agents and smoking cessation aids such as nicotine [0042, Table 5]. These compounds would be useful in a variety of methods of treatment including mania, and schizophrenia, neurological illness such as Parkinsons' and Alzheimer's Disease, that includes impaired cognition. These compounds can be used to treat negative effects after neuroleptic anaesthesia. The films dissolve quickly in the mouth depending on the thickness of the film, fillers, disintegrants and constituents, the films can dissolve as fast a 12 seconds while providing for an optimal plasma concentration in fewer than 5 minutes [Figure 5 and 6].

The reference differs from the instant claims in that although anti-Parkinsons drugs are suggested they are not exemplified or specified in the reference. However the inclusion of specific Parkinsons drugs into quickly dissolving matrices is well known in the art as seen in the '863 patent.

The '863 patent discloses a fast dissolving galanthamine formulation (abstract). The formulation comprises a carrier matrix where the active agent is present in an amount from 2 to

10%, with the support matrix up to 93% (col. 3, lin. 50-65). The support matrix includes a polymeric disintegrants as well as microcrystalline cellulose (***Ibid.***). The formulation comprises other excipients lubricants and fillers (Examples). The formulations dissolve in the oral cavity and begin to deliver their active payloads within 5 minutes (Example 6). The formulation can be used to treat chemical dependency such as nicotine dependency and cravings, Alzheimer's Dementia and associated symptoms and side effects, including impaired memory, negative sides effects of psychotropic treatments such as benzodiazepine and general mania, chronic fatigue syndrome (col. 1, lin. 43-65).

It would have been obvious to include the galanthamine salt of the '863 patent into the thin oral films of the '149 patent since the '149 reference is suggestive of cholinesterase inhibitors and discloses fast dissolving oral dosage forms. The combination would have been obvious following the suggestions of the '149 application and teachings of the '863 to quickly deliver the compounds orally. The combination would have been obvious to on of ordinary skill in the art in order delivery a quick relief to those suffering from chemical dependency.

Regarding the dissolution profile recited in the claims 30 and 31, it is the position of the Examiner that such limitations would be inherently met by the prior art. The claims recite a film comprising a galanthamine compound and a polymer dissolves within a specified time and achieves a specific plasma level. However the dissolution rate is a functional limitation that does not define a structure. The functional limitation is solely dependent on the compositional components of the claim, and as such since the only compositional components of the claim are a thin film comprising a galanthamine compound and a polymer, the compositional components art met. Since the same compounds must have the same features and function, the thin film of

the prior art combination that comprises a galanthamine compound and a polymer inherently will dissolve within 30 minutes and achieved an optimal plasma concentration. "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

The combination while discloses galanthamine derivatives in a film form is silent to multiple compounds in the strip. This however would be an obvious addition to the film in order to increase the effectiveness of the dosage form. It would be obvious to add additional similarly acting compounds to the formulation in order to increase the effectiveness of the dosage form. These other compounds are well known tine hart as seen in the '929 patent.

The '929 patent discloses oral formulations comprising a range of active agents including parasympathomimetics such as galanthamine, neostigmine and tacrine (col. 6, lin. 20-23). The dosage forms include trans-mucosal or transdermal films, or tablets (col. 4, lin. 1-20). The formulation further comprises microcrystalline cellulose, and hydroxypropylcellulose (Example 13). It would have been obvious to add these other cholinesterase inhibiting compounds to the combination of the '149 and '863 films in order to increase the effectiveness. It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in the prior art. *See* In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

One of ordinary skill in the art would have been motivated to combine the galanthamine salt of the '863 patent into the film composition of the '149 reference in order to quickly deliver the compounds to patients suffering from chemical dependency. The combination would have been obvious since both references disclose oral delivery of cholinesterase compounds in compositions comprising similar amounts of the active agents and polymer matrix components. Both references also disclose similar carrier matrices comprising flavors, filers and plasticizers. Both formulations are designed to dissolve quickly to overcome the limitation of dosage forms that require swallowing. It would have been obvious to combine the other cholinesterase inhibitory compounds of the '929 patent into the combination of the '378 and '863 reference since each patent discloses a similar composition comprising the same active agents, in similar polymeric matrices that are all delivered orally. This combination would have been obvious in order to increase the effectiveness of the dosage form in treating chemical dependency. One of ordinary skill in the art would have been motivated to combine the prior art with an expected result of a buccal film useful in the treating chemical dependency.

Response to Arguments

Applicant's arguments with respect to claims 1, 2, 7-12, 14-24, and 27-41 have been considered but are moot in view of the new ground(s) of rejection.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Friday 8:00-5:30; every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/MICAH-PAUL YOUNG/
Examiner, Art Unit 1618